

APPENDIX B -- PENDING CLAIMS

1. A composition comprising:
  - a pharmaceutical gel comprising:
    - a solvent vehicle,
    - at least one water-insoluble swellable mucoadhesive polymer,
    - at least one pH-sensitive film-forming polymer forming a film when applied to skin or a mucosal surface, and
    - at least one molecule of interest.
2. The composition of claim 1, wherein the solvent vehicle is comprised of at least 25 to 100 parts water or buffered water with 0 to 75 parts of ethanol, propylene glycol, glycerin, polyethylene glycol, or combinations thereof.
3. The composition of claim 1, wherein the water-insoluble swellable mucoadhesive polymer is polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol.
4. The composition of claim 1, wherein the water-insoluble swellable mucoadhesive polymer is NOVEON or CARBOMER.
5. The composition of claim 1, wherein the water-insoluble swellable mucoadhesive polymer is present at a concentration of from 0.1% to 20% by weight.
6. The composition of claim 1, wherein the pH-sensitive polymer is a copolymer of methacrylic acid and acrylic or methacrylic ester.
7. The composition of claim 1, wherein the pH-sensitive polymer is present at a concentration of from 0.05% to 10% by weight.
8. The composition of claim 1, wherein the pH-sensitive polymer is a EUDRAGIT polymer, or a chemical derivative thereof.

- 
9. The composition of claim 1, wherein the molecule of interest comprises an active pharmaceutical such as an antimicrobial, antiviral, antiinflammatory, antiseptic, antihistamine, a local anesthetic, a disinfectant, a keratolytic, an analgesic, an anti-migraine, an anti-fungal, a sweetener, a flavoring agent, a diagnostic agent, or combination thereof.
  10. The composition of claim 1, wherein the molecule of interest is amlexanox.
  11. The composition of claim 1, wherein the molecule of interest is triclosan.
  12. The composition of claim 1, wherein the molecule of interest is hirudin.
  13. The composition of claim 1, wherein the molecule of interest is plasmid DNA.
  14. The composition of claim 1, wherein the molecule of interest is lidocaine, benzocaine, or dyclonine.
  15. The composition of claim 1, wherein the molecule of interest is at least one benzodiazepine drug or derivative thereof.
  16. A pharmaceutical gel which when applied to the skin or mucosal surface forms a film, said gel comprising a solvent vehicle, at least one water-insoluble swellable mucoadhesive polymer, at least one pH-sensitive film-forming polymer, and at least one molecule of interest, wherein said film is formed due to changes in pH and desolvation of the polymer, and wherein said film provides for the delivery of the molecule of interest to or through the application site.
  17. The gel of claim 16, wherein the solvent vehicle is comprised of at least 25 to 100 parts water with 0 to 75 parts of ethanol, propylene glycol, glycerin, polyethylene glycol, or combinations thereof.
  18. The gel of claim 16, wherein the water-insoluble swellable mucoadhesive polymer is polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol.

19. The gel of claim 16, wherein the water-insoluble swellable mucoadhesive polymer is NOVEON or CARBOMER.
20. The gel of claim 16, wherein the water-insoluble swellable mucoadhesive polymer is present at a concentration of from 0.1% to 20% by weight.
21. The gel of claim 16, wherein the pH-sensitive polymer is a copolymer of methacrylic acid and acrylic or methacrylic ester.
22. The gel of claim 16, wherein the pH-sensitive polymer is present at a concentration of from 0.05% to 10% by weight.
23. The gel of claim 16, wherein the pH-sensitive polymer is a EUDRAGIT polymer, or chemical derivative thereof.
24. The gel of claim 16, wherein the molecule of interest comprises an active pharmaceutical such as an antimicrobial, antiviral, antiinflammatory, antiseptic, antihistamine, a local anesthetic, a disinfectant, a keratolytic, an analgesic, an anti-migraine, an anti-fungal, a sweetener, a flavoring agent, a diagnostic agent, or combination thereof.
25. The gel of claim 16, wherein the molecule of interest is amlexanox.
26. The gel of claim 16, wherein the molecule of interest is triclosan.
27. The gel of claim 16, wherein the molecule of interest is a peptide or protein.
28. The gel of claim 16, wherein the molecule of interest is hirudin.
29. The gel of claim 16, wherein the molecule of interest is plasmid DNA.

30. The gel of claim 16, wherein the molecule of interest is lidocaine, benzocaine, or dyclonine.
31. The gel of claim 16, wherein the molecule of interest is at least one benzodiazepine drug or derivative thereof.
32. The gel of claim 16, wherein the application site is the skin, mouth, vagina, nose, nasal cavity, or other accessible mucosal site.

bcc: Stephen Benoit (w/enclosure)  
Donald G. Keach (w/enclosure)  
Russell Mumper (w/enclosure)  
Michael Jay (w/enclosure)  
David L. Parker, Esq. (w/o enclosure)